For publ. in Circulation Research

AIP

AN ELECTRONIC-MECHANICAL CONTROL FOR AN INTRATHORACIC ARTIFICIAL HEART

Kirby W. Hiller B.S.*, Wolfgang Seidel M.D.**, Willem J. Kolff M.D.***

INTRODUCTION

Attempts to develop an optimum intrathoracic artificial heart pump have resulted in a family of pumps which have their moving element actuated by a pulsating fluid flow, gas or liquid. These pumps hay have a moving piston, a flexing diaphragm, or a colapsing bag as the blood pumping element. They are designed to be light-wieght and reliable. Hemolysis is minimized by techniques such as rolling diaphragm seals and non-touching surfaces. Antithrombotic characteristics are promoted by arrangement of ports to promote swirling blood flow. Further description of these pumps and the medical framework in which they must be considered can be found in the companion paper to this one.

The actuating fluid is ducted to the pump via small diameter tubing. With proper control of this driving fluid, ideal operation of the pump can be achieved. An outstanding feature of the fluid-driven pump with external control system is that great flexibility of operation is possible without adjustment of intrathoracic components.

It is the purpose of this paper to discuss some of the functions which an ideal control system for this application should perform, to describe haw a maximum flexibility "first generation" system was developed, and to indicate a possible course for future progress.

* Research Engineer, National Aeronautics And Space Administration, Lewis Research Center, Cleveland, Ohio.

** Former Fellow, Cleveland Clinic Foundation Cleveland, Ohio.

*** Head, Department of Artificial Organs, Cleveland Clinic Foundation, Cleveland, Ohio.

REQUIREMENTS OF CONTROL SYSTEM

A typical fluid actuated heart pump is shown schematically in Fig. 1.. The moving diaphragm or piston moves to the left, opening the inlet valve, and drawing in a volume of blood from the venous system; it then moves to the right, closing the inlet valve, opening the outlet valve, and forces the volume of blood into the arterial system. It might appear that a satisfactory device to pulsate the driving fluid could be quite simple. Yet when a simple, inflexible device was used for the first try, the limited success of the resulting experiments forced the conclusion that a more physiologic waveform of pumping action was required. The next step was to build a system which included many degrees of adjustability. Starting with this maximum flexibility or laboratory type system it should be easy to define the more specific requirements of future portable type systems by locking out superfluous capabilities, one-by-one, once a successful experiment is going.

One advantage of starting with a laboratory type system is that as pumping requirements change, with changing experimental philosophy, adjustments can be made without the necessity of redesigning and rebuilding a sub-component. Another advantage of the laboratory system for the preliminary work is that it can be composed of any available laboratory equipement, put together in building block form, to give unlimited new capabilities. Thus it could utilize digital and analog computers, oscilloscopes, electromechanical servo components, etc. Adopting an off-the-shelf approach with little concern for size and power consumption can promote rapid assembly and regrouping of components.

It is next in order to set down with imagination some requirements for a control system to perform this function:

EXECUTE CAPABILITIES

1* "WAVEFORM" Can be programmed for any desired waveform of actuating fluid pressure (a.f.p.).

2* "FLOW BALANCE" Permits pump inflow stroke volume to increase with increasing veinous return pressure.

3* "POSITION BALANCE" Can be made to change level of a.f.p. to rebalance pump moving element position.

4* "AMPLITUDE" Can be made to change amplitude of a.f.p. waveform.

5 "PULSE RATE" Can be made to change time base of a.f.p. waveform.

DECIDE CAPABILITIES

6* "POSITION SENSING" Senses pump moving element positon and develops instructions for changing level of a.f.p..

7* "DESIRED FLOW SENSING" Senses desired blood flow rate and develops instructions for changing amplitude and time base of a.f.p. waveform.

It is noted that all of the above capabilitues except #5 have an asterisk after the number implying that they must be implemented in a dual channel fashion. Thus a system with capabilities 1-7 would be required to perform 13 functions. 6 fual functions. and 1 single function.

An explanation of the need for the above capabilities will be given in in the following sections:

The waveform requirement #1 is the main reason for abondoning the simple system for this more complex machine. It is desired to be able. by suitable of some matrix of controls. to "write" any waveform for the two pressures. We would like to try pressure waves which are identical to those in the dog's ventricle. or as an alternative we might substitute a

* Denotes a function which must be permormed in a dual chanel manner. once for the left heart. and once for the right heart.

waveform that is sharper, or more gentle than the natural waveform. We might like the left systole to be short with a high peak and the right to be gradual with a low peak. We might want to gradually change the mode of pumping to see if the circulatory system will adapt itself to something new. Perhaps we could start with the left and right hearts pumping simultaneously and then switch over to make them pump alternately, or something between these two. In other words, since the fluid driven heart will pump in response to any type of driving pressure, we would like to exploit this advantage. Thus we can find out what are the specific requirements of a future portable control and we can do basic physiological research on the circulatory system.

The need for the flow balance requirement #2 is due to the obvious necessity of keeping the long time integrated flow from the left and right hearts equal. If the control fails to do this the patient may die, for example, from pulmonary edema. In this case we rely on a mechanism that is inherent in the circulatory system which causes the two venous return pressures to vary in proportion to the blood volume unbalance. Thus the control must permit the pump to respond with larger strokes if it experiences a higher venous return pressure, and vice versa.

Requirements #3 and #6 are written side by side because they are the "execute" and "decide" counterparts of the same capability, namely to keep the moving element of the heart pump stroking in the face of changes in blood pressure level. Refering to figure 1, we note that P_v will equal P_c except for the stiffness of the diaphragm. Assume, for the moment, that $P_v = P_c$. Now if the instantaneous value of P_v is greater than P_a, the outlet valve will open and the pump will force blood into the artery. But if the

blood pressure level in the artery increases due to stimulation of the patient and if P_c continues to execute the same waveform as before, the pressure in the ventricle may not rise high enough to open the outlet valve. Thus there will be no forward stroke but the return strokes will continue so in a few cycles the ventricle will be distended with blood and pumping will cease. Obiously the control must permit an operator to change the d.c* level of P_c to keep the pump in balance - this is capability #3. Moreover it would be desirable for the control to "know" what the output element is doing and to "decide" which changes to make for corrective action- this is capability #6.

Requirement #7 is written beside requirements #4 and #5 since they are the "decide"and "execute" counterparts of the same capability, namely, to change blood flow rate. Capabilities #4 and #5 make it possible to vary the flow rate from the artificial heart, either by increased volume of each stroke, or by increased frequency of strokes. The pulse rate requirement #5 implies that the time base of the pressure waveform can be varried. Specifically, it is desired to be able to independently vary the time base of the two phases of the waveform, namely the systole and the diastole. Thus the relative dwell of systole and diastole can be varied as a function of pulse rate. This will enable us to increase pulse rate by shortening diastole period only with systole period held constant, or vice versa, or something between these two.

The stroke amplitude capability #4 lets us change flow rate by changing the amplitude of the a.c. component of the pressure waveform. Adding this a.c. component of controlled pressure to the d.c. component

* d.c. and a.c. (direct current and alternating current) are used here to denote the slowly varying or relatively fixed and the rapidly varying components of the pressure wave form.

from capability #3 gives the output pressure. Capability #7 implies that the control has a way of "knowing" the patient's desired blood flow rate and can "decide" what changes to make in amplitude and pulse rate for corrective action.

In the above paragraphs we have explained what these seven requirements of the control system can mean to the patient and to the research director: some of them are necessary for survival of the patient, others are necessary for his comfort, still others open up new areas of physiological research

It is next of interest to note what degree of effort these capabilities, or their absence, might require from an operator of this equipment. To this end we set down the following table:

FUNCTION		RESTING PATIENT	ACTIVE PATIENT
1*	Waveform	Initial	Initial
2*	Flow Balance	None	None
3*	Position Balance	Continual	Continual
4*	Amplitude	Initial	Continual
5	Pulse Rate	Initial	Continual
6*	Postion Sensing	None	None
7*	Desired Flow Sensing	None	None
3*	Plus 6*	None	None
4*	Plus 5 Plus 7*	None	None

The first thing to note about the above table is that the various capabilities, taken one at a time, require the types of effort indicated from the equipment operator: but when these capabilities are taken in groups like 3 plus 6 the effort required from the operator is

reduced to nothing. To make the picture perfectly realistic it is best to consider these capabilities in reasonable groupings: for example a system with capabilities 1-5 would probably constitute a minimum essential system. With a 1-5 system the operator whose patient was resting would have to perform two functions continually: adjust d.c. levels in two chanels. For an active patient he would have to perform five functions continually: adjust two levels, two amplitudes, and one pulse rate.

For a somewhat more complete system having capabilities 1-6 the operator would have no functions to perform continually for a resting patient, and he would have three functions to perform for an active patient; the control would now be adjusting its own levels, but not its amplitudes and pulse rate.

For a system with capabilities 1-7 the operator would have no functions to perform continually for an active or a resting patient. The system would now be adjusting its own levels, amplitudes, and pulse rate. This, then, would be a completely automatic, self-monitoring, and self-correcting system.

The system to be described in this paper has capabilities 1-6 when used with a bellofram heart and has capabilities 1-5 when used with a sack type heart. The absence of capability #6 (Position sensing) does not arise from the lack of electronic capability to take a signal idicative of moving element position and transform this to a signal suitable for changing d.c. level of the actuating fluid pressure: instead it stems from the lack of a position sensing transducer for the sack heart. A development program is underway, however, and a transducer composed of

two induction coils impregnated in the two sides of the plastic bag seems a likely prospect. In the case of the bellofram heart, the positon sensing job was simpler since the output element was positioned by a shaft connecting two pistons; thus an "off-the-shelf" variable reluctance psoition transducer could be used.

To implement capability #7 has not yet been seriously considered. Electronically this capability could be easilly handled in a system which incorporated an analog computer, provided only that the signal indicative of required blood flow rate were available. Thus, again, the missing link is the specialized transducer system to sense this paramater. To sense something approximately correct like blood oxygen concentration could probably be done with existing medical electronic instrumentation. In any case capability #7 is within the realm of possible implementation within a few months if interest were high but has not yet received much attention.

It is of interest that, with the exception of the "required blood flow rate" transducer, all of the equipement to implement capabilities 1-7 for a strictly laboratory system is available on the basis of off-the-shelf subcomponents; these, of course, must be selected and assembled in a sensibly engineered system. Scientific progress in the aerospace industry is making these subcomponents available as better subassemblies making it an easier job to assemble such a system. Within one year enough new equipement has become available to make considerable improvement possible in the design of the next system of this type. One example of this is the transistorized desk-top analog computer, recently available, which can perform many of the functions required in this type of system.

GENERAL DESCRIPTION OF ELECTRONIC-MECHANICAL PRESSURE CONTROLLER

A control system was built along the lines of a compromise design between the laboratory and the portable approach. It did not depend upon an analog computer installation although analog computer type circuits were used in some of its components. As a consequence it had the advantage of a degree of semi-portability. At the same time this advantage was baught at the price of requiring specialized development of some circuits.

The system, which is housed in a single relay rack on castors, includes all equipement necessary for the repetative generation of two pneumatic pressures to drive two bellofram or sack type hearts. It requires external connections to electric power and to a source of positive and negative pneumatic pressure. A photograph of the equipement in use in an artificial heart experiment with a dog is shown in Figure 2.

For monitoring purposes a two chanel oscilloscope with long persistence screen was included at eye level for a seated operator. Below this was installed a control panel consisting of five precision potentiometers as necessary to adjust the system as per requirements 3*,4*, and 5 above. Below the control panel were installed two matricees of potentiometers on pull-out drawers: these are used to program the system for the desired waveforms of driving pressure as per requirement 1* above: the operator in the photograph is shown making an adjustment in one of these matricees. Besides these components, which require the main manipulation, others were located for minimum wiring complexity, etc.

Care was taken throughout to place controls for the left heart on the operator's left, and vice versa. The controls were also color-coded using red for the left heart, blue for the right. The general approach in construction was to use proven techniques to make a building block system from off-the-shelf components. In no case was flexibility sacrificed to the benefit of simplicity.

Hillea., Et Al. - 10

[illegible]

Two of the types of mechanisms which could be used to generate variable fluid pressure in a closed chamber like the artificial heart with its input tubing are as follows:

1. A piston-in-cylinder type pump as shown in figure 3 could be used. This could be driven mechanically by a cam-and-roller for a fixed waveform application or by a servo system for a variable waveform. Thus it would be a closed system; there would be no fluid loss. It would also represent a low energy consumption system. The ultimate portable system may use something close to this principle.

The present [illegible] indicate an approach [illegible] had an inverted set of advantages and disadvantages; namely a maximum flexibility system preferably with high dynamic response to allow freedom of waveform selection and with little concern for power consumption. This led to a system with minimum inertia of controlled parts and, incidentally, one which must be driven by a motor of higher power, namely:

2. A throttling system as shown in figure 4. Here pressure in the chamber is varied by alternately connecting it to a high pressure supply or to a low pressure supply through a variable area orifice. This can be made a zero fluid loss system by interposing the pump between the high and low pressure supply tanks. The valves could be either continuously variable (proportional type) or they could be open-closed (on - off). In the case of on - off operation a variable waveform of output pressure could be obtained only if the valves could be cycled many times during one heart beat. If the valves were open-

and would be typical test curve for each unit, output pressure would be limited to just the waveform, a spike-squared square wave.

For this system a proportional type valve was chosen which had a construction that can be shown schematically as in figure 5. This is really a specific example of the more general two moving element throttling schematic of figure 4. In this case the two valves have been ganged together on one armature. This servovalve is controlled by an electronic servoamplifier with a push-pull output stage. Current in the coil around the armature polarizes the armature so that it tends to work within the permanent magnet pole pieces. Total armature motion is of the order of 0.3 millimeters at the point where the spools are connected. Dynamic response of the servovalve is flat with 1 a.c. to 100 cycles per second passband. In the discussion that follows the servovalve will be illustrated by a block diagram type symbol. It is noted that the input parameter to the servo valve is a current through the coil and the output is a flow area of an orifice. The servovalve will therefore be shown as in figure 6. Since the servoamplifier is a voltage input, current output device, it and the servovalve can be shown as in figure 7.

To improve the reliability of positioning the servovalve a feedback loop is introduced around the amplifier-valve combination as shown in figure 8. Valve position is measured by a differential transformer followed by a phase sensitive demodulator to give a d.c. output voltage proportional to valve position. This valve position signal is subtracted from a desired valve position signal to give an error voltage which is

indicative of whether actual valve position is in 1:1 correspondence with desired valve position. The error voltage drives the valve to a position where actual and desired position are in correspondence.

The more important loop around this is the pressure feedback loop as shown in figure 9. Here output pressure from the servovalve is sensed with a variable reluctance type pressure transducer and fed back to a comparison circuit. The resulting system is the pressure servo, two of which are required, one for each side of the heart. Some of its overall characteristics are worth considering. Being a high gain feedback system it is immune to many of the shortcommings of simpler open loop systems because the input "knows" what the output is doing. If supply pressure changes the valve simply moves to whatever position is necessary for output pressure to be in 1:1 correspondence with input voltage. It is reasonably immune to changes in valve friction, amplifier gain, load leakage, supply pressure, power line voltage, in short most difficulties which affect the foreward path. It is not tolerant, however, to difficulties in the feedback paths, particularly the outer loop feedback path. Thus if the feedback paths are made simple and reliable such a system can be trusted to perform as a faithful slave or servo. Beyond this point the two loop pressure servo will be considered as a "black box" with an input of a d.c. voltage and an output of a pneumatic pressure, as shown in figure 10.

PROGRAMABLE FUNCTION GENERATOR

With two pressure servos of the type just described the addition of one a suitable device to supply the necessary two input voltages would give the three principle components of the required control system for the fluid driven hearts. A block diagram of such a system

is given in figure 11.

Several requirements must be met by the function generator.

1. It had to permit completely arbitrary programming of the two voltages with the program being repeated cyclically.

2. The program was to be run with a variable time base to give a a variable pulse rate.

2a. The time base was to be set up so that during one cycle the function was to be swept a two speeds, one speed for the systole and one speed for the diastole.

A proposed schedule was set up for the systole and diastole sweeping speeds as shown in figure 12. Thus at low pulse rates diastole period is to be twice as long as systole period, while at high pulse rates a 1:1 ratio of periods is to prevail.

To satisfy this set of requirements a multi-gang motor driven potentiometer was set up as shown in Fig. 13. The two potentiometers have 24 taps each at 15° intervals. If these taps are supplied with 24 constant voltages from low impedance sources then the output voltages will be a twenty-four straight line segment interpolation between successive taps as shown in Fig. 14. The potentiometers chosen were long life conductive plastic units with a usable life of over 100,000.000 cycles. One gives the voltage function for the left pressure servo, the other for the right pressure servo. Two matricees of 24 fixed potentiometers each were set up to power the taps of these cycling pots. These could be programmed to any desired voltage function that can be reasonably approximated by 24 straight line segments.

A two phase servo motor was used to drive the cycling potentiometer and feedback from a tachometer was used to make a responsive closed-loop speed control system. To satisfy the requirement for independent sweeping speeds for systole and diastole a cam actuated microswitch was used to select one of two input voltages for the comparison circuit of the amplifier. These voltages, in turn. were derived from a single manual potentiometer on the control panel which was calibrated for pulse rate in beats per minute. The system was set up for 12 taps of each cycling pot to be assigned to systole and 12 taps for diastole. Thus at low pulse rates the motor sweeps twice as fast through the 12 systole taps as it does through the 12 diastole taps. Pulse rate increase is acchieved mainly through speeding up the diastole sweeping speed as the program of Fig. 12 indicates.

OVERALL SYSTEM

A sumarized three bloc diagram for the complete system is shown in figure 11. The function generator is the starting point for the system and it in turn receives a "desired pulse rate" instruction from the equipement operator. The two output voltages from the function generator then drive the two pressure servos, their outputs being the two controlled pressures which drive the two artificial hearts.

The picture of Fig. 11 is symplified and can be improved by inserting some of the controls which give the system some of the capabilities described earlier.

Requirement #3 calls for the capability to change the d.c. level of actuating fluid pressures. This can be done by simply adding two d.c. voltages to the inputs of the two pressure servos. This modification is shown in Fig. 12. The input to the servo in now the sum of the output of the function generator and the d.c. level control. It can now be shown that such a pressure servo can permit other things to be done with an artificial heart besides repetative cycling. If the voltage from the function generator is held to zero the output pressure of the servo will follow the d.c. level control only: thus it can be set at any positive or negative value as the operator chooses. Output pressure will follow level control position instantly and with precision. This can now be used for very slow cycling of the heart, for holding it in any desired position, for calibrating the heart, for stroking the heart just once to free it of trapped air, etc. The output from such a pressure servo, incadentally, can be used to drive any other type of pressure input equipement with the input function taken manually, from the existing function generator, or

from any other electronic function generator.

Requirement #4 calls for changing the amplitude of the fluid pressure waveform. This requires only that the amplitude of the voltage fed from the function generator to the pressure servo be under manual control. This is done by simply introducing two amplitude controls as shown in figure 16. This feature permits a smooth onset of beating of the two hearts: by turning up both amplitudes carefully the operator can follow some desired startup program.

Requirement #6 implies that the control must sense heart pump moving element position and automatically generate its own level signal for repositioning purposes. In other words, returning to figure 16, some automatic device must be found which will "know" what the output element is doing and will put a third signal into the summing junction at the pressure servo input. This signal should not be an instantaneous type signal like the other signals in the system but it should be similar to the action of a human operator making an adjustment; after a few cycles of stroking too far toward one end of travel it starts making a correction in the proper direction. Of course the position transducer in the heart pump is a first requirement. This then requires electrical communication with the heart pump. In the case of the bellofram heart an off-the-shelf variable reluctance position transducer can be used; in the case of the bag heart induction coils are used. In either case the 5 Kc a.c. excitation current and the a.c. output signal are communicated to the heart via small diameter insulated wires inside the pneumatic line. The a.c. signal form the transducer is demodulated to give a d.c. output voltage and then fed to the summing junction

via a long time constant electronic filter circuit. The resulting configuration is shown in figure .. It is noted that the output voltage from the demodulator is an instantaneous signal indicative of heart pump position, hence a good parameter for monitoring purposes; if the two pump positions are simultaneously displayed on a two chanel oscilloscope while pumping is in progress it becomes obvious if one pump is in trouble and what to do for correction. The purpose of the filter on the output of the demodulator is to provide the slowly responding output necessary for this type of corrective action.

ADDITIONAL CAPABILITIES

The control system developed for this application had a few additional capabilities beyond those which were strictly necessary to satisfy the requirements set down above. These additional capabilities are in the area of readout signals and displays.

Specifically, it was noted that since pump moving element postion was available it should be possible to use this signal for more than a simple position display. For one thing in a piston and cylinder pump the instantaneous flow rate into or out of the pump is simply the product of piston area and instantaneous piston velocity:

$$Q\ (\text{cm.}^3/\text{sec.}) = A_p\ (\text{cm.}^2)\ v\ (\text{cm./sec.})$$

If the piston velocity is positive fluid is being pumped out of the cylinder; if it is negative fluid is being drawn into the cylinder. This same relation applies for a bag type heart if we postulate an appropriately sized virtual piston area. In any case the piston position signal was differentiated electronically and multiplied by an appropriate constant to give the instantaneous flow rate signal. This signal was made available on a test jack for monitoring purposes. What it really shows is instantaneous flow rate in the heart which is the sum of arteriel and venous instantaneous flow rates. The positive peaks of this flow signal are the arteriel flow, the negative peaks are venous flow. A diagram to illustrate these signals is shown in Fig. [illegible]. The next step was to electronically calculate an averaged blood flow rate for the two hearts and present the result for visual display. This required rectifying the heart flow rate signal so that it shows the

sum of arterial and venous instantaneous flows rather than their difference and then filtering the resulting voltage with a slow filter. The result is then displayed on a galvanometer calibrated in 100 divisions which represents "percent of maximum blood flow rate". The overall system with these additional readout elements is shown in Fig. 19. This then represents the complete system which was developed for this application. This system has been shown to adequately fulfill requirements 1-6 with a bellofram heart and will soon be extended to do the same with a bag type heart. It permits smooth startup and air removal from the artificial hearts; it permits exact monitoring of heart pump moving element position, and pump flow rates; and it operates with a great enough degree of self-adjustement to satisfy the requirements of most present day intrathoracic fluid driven artificial heart experiments.

FUTURE RECCOMENDATIONS

The "first generation" system here described is presently a working system, the only one of its kind, and destined to see much future use. Enough experience was gained in its construction and use to point out many areas for improvement in future work of this type.

Starting from the top, it should be recognized that maintenance, and upgrading of such a system can be handled only in an organization which is staffed with persons having the equivelent of an electrical or mechanical engineering education with considerable electronics and servomechanisms experience. The services of electronic technicians are also requisite.

Future machines should be built with a view toward high reliability of operation and should, at the same time, include a "satisfactory operation monitor". This monitor should have the capability of detecting a malfunction in either chanel and , when necessary, should automatically switch over to a standby machine.

This machine required external connections to 110 v and to positive and negative pressure supplies. For neater packaging, the next system should include its own internal compressor/vacuum pump, suitably vibration and accoustically isolated. This pneumatic system should be usable with helium, CO_2, and air.

In designing future machines it is reccomended that the system consist of a two chanel pressure servo with a "satisfactory operation monitor" and an internal pressure/vacuum system, as mentioned above, plus a desk top type analog computer, and a central control panel for coordinating the system. The analog computer should be obtained with

removable problem boards and should be of good enough quality to permit its use with other medical dynamic simulation and controls type research projects.

A research organization seriously interested in doing artificial heart research directed toward human patients should have at least two such machines, with one available as a standby. In view of the long term nature of this and of successful animal experiments, several machines of this type may soon be part of the scene in medical laboratories doing circulation and artificial heart research.